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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,198	08/10/2001	James Arthur Hoffmann	X12383N	6700
25885	7590	05/27/2005		
ELI LILLY AND COMPANY PATENT DIVISION P.O. BOX 6288 INDIANAPOLIS, IN 46206-6288				
			EXAMINER DEBERRY, REGINA M	
			ART UNIT 1647	PAPER NUMBER

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/928,198

Applicant(s)

HOFFMANN ET AL

Examiner

Regina M. DeBerry

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 128-131 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 128-131 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 09 March 2005 has been entered.

Status of Application, Amendments and/or Claims

The amendment filed 18 May 2005 has been entered in full. New claims 129-131 were added. Claims 128-131 are under examination.

Information Disclosure Statement

The information disclosure statement(s) (IDS) filed 18 May 2004 and 25 May 2004 were received and comply with the provisions of 37 CFR §§1.97 and 1.98. They have been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 103

Claim 128 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Keene *et al.*, The Journal of Biological Chemistry Vol. 264/9: 4769-4775 (reference of record) in view of Skrabanja *et al.*, EP 0853 945 A1 (reference of record) and Andya *et al.*, US Patent No. 6,267,958 B1 (reference of record). The basis for this rejection is set forth at pages 5-7 of the previous Office Action (18 March 2004).

Applicant fails to present new arguments regarding the instant rejection. The instant rejection shall be maintained for reasons of record.

Double Patenting

Claim 128 remains provisionally rejected under the judicially created doctrine of double patenting over claims 159 and 160 of copending Application No. 09/744,431 in view of Keene *et al.*, The Journal of Biological Chemistry Vol. 264/9: 4769-4775 (1989)(reference of record), Skrabanja *et al.*, EP 0853 945 A1 (reference of record) and Andya *et al.*, US Patent No. 6,267,958 B1 (reference of record). This is a provisional double patenting rejection since the conflicting claims have not yet been patented. The basis for this rejection is set forth at pages 7-9 of the previous Office Action (18 March 2004).

Applicant fails to present new arguments regarding the instant rejection. The instant rejection shall be maintained for reasons of record.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description, New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New claims 129-131 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.** Applicant's amendment, filed 18 May 2004, asserts that no new matter has been added.

The specification as originally filed does not provide support for the invention as now claimed: "the pharmaceutically acceptable solution formulation of claim 128, wherein the solution is suitable for administration without being reconstituted by the patient" (claim 29) and "the pharmaceutically acceptable, solution formulation of claim 128, wherein the solution is prepared by reconstitution by the patient (claim 131). Applicant directs support to page 38, line 23-30 for the written description for the above-mentioned "limitations". This is not found persuasive. The instant specification (page 38, line 23-30) teaches that a vial of lyophilized FSH (or FSH variant) is reconstituted with a second vial containing the aqueous diluent. The newly submitted claims read on the **solution** being reconstituted (or not reconstituted). The newly submitted claims now recite limitations which were not disclosed in the specification as originally filed, and now change the scope of the instant disclosure as filed.

The specification as originally filed does not provide support for the invention as now claimed: "the pharmaceutically acceptable, solution formulation of claim 128, wherein the solution is contained in a sealed vial" (claim 130). Applicant states that support for the new claim 130 can be found on page 17, lines 31-33 in the definition of a vial. Applicant states that retaining the solution in a sterile state indicates that the vial is sealed. This is not found persuasive. The newly submitted claim now recites limitations which were not disclosed in the specification as originally filed, and now changes the scope of the instant disclosure as filed.

The specification as filed does not provide a written description or set forth the metes and bounds of this "limitations". Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to provide specific written support for the "limitations" indicated above or rely upon the limitations set forth in the specification as filed.

Conclusion

No claims are allowed.

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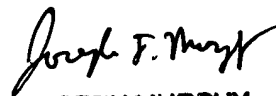
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RMD
5/23/05



JOSEPH MURPHY
PATENT EXAMINER